September 1, 2020

United Healthcare via Email: mpq@uhc.com
Medical Policy Department
9500 Bren Road East
Minnetonka, MN 55343

Re: Epiduroscopy, Epidural Lysis of Adhesions and Discography, Policy Number 2020T0206S

To Whom It May Concern:

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to comment on your policy Epiduroscopy, Epidural Lysis of Adhesions and Discography, Policy Number 2020T0206S.

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

While we agree with the classification of other procedures as unproven or not medically necessary, we do not agree with this classification for provocative discography. Provocative discography is well-established and has a strong extant evidence base. It is an important tool to assist in the diagnosis of chronic low back pain refractory to conservative treatment. Appropriate coverage criteria and a thorough description of the supporting evidence are outlined in the North American Spine Society’s Coverage Policy Recommendations on Discography (attached).

The undersigned societies appreciate the opportunity to provide these comments and would welcome the opportunity to work with United Healthcare to establish a reasonable coverage policy that will eliminate inappropriate utilization while preserving access to provocative discography for appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at the Spine Intervention Society, at bduszynski@SpineIntervention.org.

Sincerely,

American Academy of Physical Medicine and Rehabilitation
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Spine Radiology

North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology
Spine Intervention Society

Attachment:
Discography
Introduction
North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 9/26/16; information and data available after 9/26/16 is thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology
The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Background Information
Chronic low back and neck pain have been a significant problem in the population that continues to increase the overall cost of the health care delivery system. The diagnosis of discogenic pain in both the cervical and lumbar spine can be difficult since patients often present with or without radicular symptoms. Recently, diagnosis and subsequent treatment have been advanced with newer imaging studies, and MRI has proven to be extremely useful in defining the disc pathoanatomy. Discography is often used to distinguish a painful from a non-painful intervertebral disc. Combining positive MRI imaging with provocation discography has led to treatment opportunities for many patients.1-4

Unfortunately, the degenerative appearance of the disc and the presence of annular fissuring often do not correlate with pain generation. In the lumbar spine discogenic pain was found in 22% of the patients presenting with chronic low back pain.5 This leads to the inevitable dilemma of diagnosing painful degenerative discs from non-painful degenerative discs. Discography has been used to correlate MRI degenerative findings with pain experienced by the patient.1,2 The paucity of prospective studies in the literature further compounds the issue. The lack of an adequate control for comparison has made it even more difficult.6,7 As was pointed out in one review, one of the hallmarks of a positive discogram is concordant pain provocation, which is not possible in people without low back pain.8-10 Others have hypothesized that surgical outcomes should be the “gold standard” by which to judge the relevance of discography.11-14 Also, the presence or absence of fusion was not evaluated.9 When taking into account the presence of a solid arthrodesis, false positive scores decrease.1-4

With the introduction of manometric pressure measurements and subsequent reanalysis, the false positive rate for lumbar discography was markedly reduced.10,15-16

In 1995, NASS developed a position statement on lumbar discography.17 This was updated after a comprehensive review in 2003.18 There were no major changes at that time. Based on the United States Preventive Services Task Force criteria, the indicated evidence has been determined to be level 2 for lumbar discography.4 The incidence of discogenic pain was found to be 26% and false positive rates with discography were 9.3%.6 Research indicates that the false positive rate for lumbar discography should be 0 to 10% when performed using small volumes (<3.0 cc) and pressures <50 PSI.15

Scope and Clinical Indications
Lumbar and Cervical Disc Stimulation (Provocation Discography) are indicated when all of the following criteria are met:

1. The presence of pain and some functional disability for a period of at least 6 months despite conservative therapy. This pain needs to be in a location that could reasonably be caused by the disc (ie, axial neck or low back, with or without somatic referred pain).
2. The suspected source of pain identified through other diagnostic imaging testing (eg, MRI, myelography, CT) needs to be in-
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**Rationale**

**Lumbar Discography**

Lumbar Discography is a tool utilized to assist in the diagnosis of chronic low back pain refractory to conservative modalities. In Item 1, the rationale for coverage for lumbar discography is based on current practice patterns and known disc pain referral patterns. In Items 2 and 3, because of the known shortcomings and risks of discography, if a clear cause of the patient’s pain is known based on imaging studies, or if performing this procedure will not change the treatment, then the need for discography is eliminated. There has been a significant amount of literature published on complication rates for discography. Complications can include disc injury, discitis, dural tears, bleeding, epidural abscess, chemical meningitis, allergic reaction to the dye, and injury to the nerve root. In the NASS statement of 1988, the rate of discitis was found to be 0.1-0.2%. Studies have provided an accurate diagnosis and when there is no evidence of infection, tumor, or cord compression.

**Cervical Discography**

Cervical discography is intended to identify a painful cervical disc as well as identify internal derangements. Siebenrock et al in 1994 found 75% of patients at one-year post cervical fusion diagnosed by discography had good to excellent results. This increased to 86% at two-year follow up. Other outcome studies have shown positive results.

Zheng et al concluded that MRI can be used as a screening test in patients presenting with cervical discogenic pain, whereas discography can be used as an adjunct confirmatory test, avoiding fusion at unnecessary levels. Also, discography was found to be helpful in differentiating between painful disc and asymptomatic discs in the older population. However, Bogduk and Aprill found that due to the high prevalence of cervical zygapophysial joint pain, the false-positive rate of cervical discography was unacceptably high if zygapophysial joint pain had not first been excluded. In the 56 patients studied, disc stimulation was clearly positive in only 11 (20%). It was false positive in 23 patients (41%) whose pain was relieved by zygapophysial joint blocks. These figures suggest a false-positive rate of 72% (23/32) and a positive predictive value of only 32% (11/34), unless zygapophysial joint pain is first excluded before undertaking cervical disc stimulation.

The greatest concern with cervical discography is the lack of a standardized grading system for what constitutes as a positive response. In a systematic review by Onyewu et al, 41 manuscripts were reviewed. As he noted in the review, there is a paucity of literature, which limits the evaluation of cervical discography. More high quality studies need to be developed in order to determine the utility of this procedure in the cervical spine. For a patient who has failed all conservative measures, the following recommendations can be made:

1. **Cervical discography is appropriate for patients who have failed 6 months of conservative measures for whom no imaging studies have provided an accurate diagnosis and when there is no evidence of infection, tumor, or cord compression.**
2. **The test is deemed positive only if stimulation of the target disc reproduces pain at 7/10 on a VAS modified 10 point scale or 70% of the most severe pain the patient experiences at low pressure levels and two adjacent discs do not produce any pain at all with low volume and low pressure injection.**

**Functional Anesthetic Discography Background**

Anesthetic discography has been suggested as an adjunct or a stand-alone test to determine a painful disc and/or painful segments in patients with a previous fusion. Bavtynski et al did a prospective review of 182 painful segments in 111 patients. The results showed that 74% of patients with leaking discs experienced near complete or complete pain relief after injection with intradiscal lidocaine. Although in contained discs, pain relief was limited. As a subset, Kimura et al injected segments with previous anterior interbody fusions. These patients underwent revision surgery with long-term pain relief. This was also discussed in one case study.

However, other studies have shown the contrary. Derby et al found no difference between injection of a local anesthetic and con-

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In another prospective clinical series, the outcomes were limited with no definite clinical indications. They do recommend further evaluation to determine the clinical efficiency of the test.

Of greatest concern are the effects of the anesthetic agents in the intervertebral disc cells. Iwasaki et al. studied the effects of analgesic injection on rabbit intervertebral discs. There was no cell degeneration beyond the mechanical damage of pressurization of the disc. In contrast, other studies looking at the effects of anesthetic agents on bovine and human intervertebral cells showed cell death which could lead to further intervertebral degeneration. In a separate study, a steroid injection into the disc was compared with an anesthetic injection with no significant benefit.

Although several case studies have shown the efficiency of further delineating the painful segment in both the nonoperated and the previously operated spine, sufficient literature is not available to provide coverage recommendations for functional anesthetic discography. Most consist of case studies with little Level 2 evidence to support or to reject its use. Of concern is the effect of the anesthetic agents on the cell integrity of the intervertebral disc leading to further degeneration. Anesthetic discography does appear to be helpful to determine pseudarthrosis in a previously operated segment (especially previous interbody fusions). In this situation, further degeneration is not a concern. It may be used as an adjunct to provocative discography to determine surgical decision-making in some cases. However, the effects in the intervertebral disc cells should be considered when doing so.

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1. Horton WC, Daftari TK. Which disc as visualized by magnetic resonance imaging is actually a source of pain? A correlation between magnetic resonance imaging and discography. Spine. 1992; 17:S164-S171.
22. Carragee EJ, Barcohana B, Alamin T, van den Haak E. Prospective controlled study of the development of lower back pain in previously asymptomatic patients.

Additional Resources

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**Comments**

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.